

The opinion in support of the decision entered today was not written for publication and is not binding precedent of the Board.

Paper No. 31

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte GARY A. LATTIN, GARY A. MESSER,
MARK R. BILITZ, JOHN R. PEERY
and J. RICHARD GYORY

Appeal No. 2001-0661
Application No. 08/480,232

ON BRIEF

Before FRANKFORT, STAAB, and NASE, Administrative Patent Judges.

STAAB, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on an appeal from the decision of the examiner twice rejecting claims 1-56, all the claims currently pending in the application. As the examiner has subsequently allowed claims 48-50 (see page 2 of the examiner's answer), only the rejections of claims 1-47 and 51-56 remain before us for review.

DISCUSSION

1. The anticipation rejection

Looking first at claim 1, this claim is directed to an electrotransport agent delivery device for delivering an agent through a body surface, wherein the device comprises an active electrode, a return electrode, circuitry which controls current output of the device, and a source of electrical energy. The device is further defined as having at least two rigid regions which are placed against the body surface at spaced apart locations, and flexible means physically and electronically connecting the rigid regions to one another and permitting the rigid regions to move independently with respect to each other.

In rejecting claim 1 as being anticipated by Sibalis, the examiner relies on the Figures 14-16 embodiments thereof. The examiner considers that the terms "rigid" and "flexible" are relative terms and in the absence of specific flexural values can be considered to have essentially any value desired. The examiner further considers that the petal configurations of Sibalis would inherently be more rigid at the thicker portions than at the thinner "hinge" or "web" portions. Based on these considerations, the examiner concludes that the Figures 14-16 embodiments of Sibalis anticipate the claim.

We appreciate the examiner's position that the terms "rigid" and "flexible" may be viewed as being relative terms. We also appreciate the examiner's position that the "petal" or main body sections of the Figure 14-16 embodiments of Sibalis would appear to inherently be more rigid than the unnumbered "hinge" or "web" portions connecting said

“petal” regions. Be that as it may, we nonetheless share appellants’ view that these circumstances alone are insufficient to establish anticipation of the subject matter of claim 1. Our determination in this regard hinges on exactly what the broadest reasonable interpretation of the term “rigid region” in claim 1 would be to one of ordinary skill in the art.

In proceeding before it, the PTO applies to the verbiage of claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicants’ specification. *In re Morris*, 127 F.3d 1048, 1054, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997). We are informed by appellants’ disclosure that the housings 12, 14, which correspond to the “rigid regions” of claim 1

are substantially incapable of conforming to the contour of the underlying skin surface and, but for hinge 16, would eventually cause the underlying adhesive sheet 18 . . . either to peel away from the skin, or pull on the skin and thereby cause discomfort for the wearer as a result of normal body movement. [Specification, page 12.]

We are further informed by appellants’ disclosure that

[t]he term “rigid” when used in describing a portion or zone of an electrotransport system means that the portion or zone has sufficient stiffness so as to be incapable of adhering to a body surface (e.g., the skin) of a patient using a biocompatible and pharmaceutically acceptable contact adhesive without injury to the body surface or identifiable patient discomfort, throughout the normal range of body motion. In other words, a “rigid” zone of an electrotransport system is prone to peel from the skin, or alternatively to undergo delamination of adjacent layers within the rigid zone of the system, thereby interfering with the desired agent or delivery system. [Specification, page 13.]

In light of the above, it is apparent to us that the term “rigid” as used within the context of appellants’ disclosed invention cannot properly be considered to have essentially any value, as proposed by the examiner, but instead requires a certain minimum degree of flexural rigidity or stiffness. More particularly, the degree of stiffness required is such that a delivery device of such overall flexural rigidity would peel or pull away from the skin as a result of normal body movement and thereby cause injury or discomfort for the wearer as a result of normal body movement.

Turning to Sibalis, the “Background” section of the specification explains that prior to the Sibalis invention, there were no transdermal drug applicators constructed “to compensate for one’s movement and skin stretch so as to preclude loosening” (column 3, lines 4-8). Accordingly, one of the objectives of Sibalis is to provide a transdermal drug applicator of very shallow layered construction that overcomes this deficiency in the prior art (column 1, lines 26-39). The first layer is a microporous or semipermeable membrane 22 through which the medicament migrates to be deposited on the skin. The second layer consists of a “flexible pad, pouch or other type reservoir 24” containing the drug to be administered (column 5, lines 13-15). The next layer above the reservoir 24 is an extended contact 26 which is “preferably body-conformable, to permit applicator 10 . . . to be curved or bent to conform to the shaped surface of the skin” (column 5, 37-40). Next, a battery 28 is provided, which may be a “very thin, flexible sheet[]” (column 6, line 8) whose selection depends on such factors as “the degree of conformability desired”

(column 6, line 18). Finally, a cover 12 is provided that encloses all of the layers and “is made from a flexible conductive plastic material” (column 6, lines 25-27). As to the Figures 14-16 “petal” embodiments relied upon by the examiner, based on the description thereof as set forth at column 10, lines 27-64, the individual sections or “petals” of these embodiments would appear to be of the same basic layered construction as the earlier described applicators with the exception that in the Figure 14 and Figure 15 embodiments the reservoir comprises a plurality of discrete relatively small cells rather than a single large cell. According to Sibalis, the plural cell construction “lends itself to greater flexibility and ability of the applicator to conform to the contours of various parts of the body” (column 10, lines 27-31).

When the claim term “rigid region” is properly interpreted in light of appellant’s underlying specification, it is at best unclear whether the individual sections or “petals” of the Figures 14-16 embodiments of Sibalis possess the degree of flexural rigidity required by that claim term.¹ It follows from such uncertainty as to the rigidity of the sections or “petals” that the standing anticipation rejection of claim 1 cannot be sustained. Claims 7-13, 17-20 and 30 depend from claim 1, hence the anticipation rejection thereof based on Sibalis likewise cannot be sustained.

¹Based on the aims and objectives of Sibalis, it appears to us more likely that the individual sections or “petals” of the Figures 14-16 embodiments do not possess the degree of flexural rigidity required by the claim term “rigid region.”

The anticipation rejection of independent claim 34 and claims 40-47 that depend therefrom cannot be sustained for essentially the same reasons as discussed above in connection with claim 1. In this regard, the limitation of claim 34 calling for an electrotransport agent delivery device comprising, among other things, at least two “substantially rigid regions” and flexible means extending between the regions to permit relative movement of the rigid regions finds no clear response in Sibalis.

We reach an opposite conclusion with respect to the anticipation rejection of independent claim 21 based on Sibalis. Appellants’ only argument in favor of claim 21 is that Sibalis does not disclose two rigid regions. However, this argument fails at the outset with respect to claim 21 because it is predicated on a limitation that does not appear in the claim. See *In re Self*, 671 F.2d 1344, 1348, 213 USPQ 1, 5 (CCPA 1982) (features not claimed may not be relied upon in support of patentability). Unlike claims 1 and 34, claim 21 does not require that the device comprise at least two rigid regions. Instead, it merely requires that the device comprises “at least two regions.” The individual “petals” or body sections of the Figure 14-16 embodiments clearly comprise “regions” as called for in claim 21.

The anticipation rejection of claims 27-29 that depend from claim 21 likewise will be sustained because these claims have not been separately argued. In any event, the thin webs connecting the “petals” or body sections of the Figure 14-16 embodiments of Sibalis reasonably appear to meet the flexible means limitations set forth in claims 27-29.

2. The obviousness rejection

Claims 2-6, 14-16 and 31-33 depend from independent claim 1 and claims 35-39 depend from independent claim 34. In addition to not anticipating the requirement of independent claim 1 calling for “rigid regions” and the requirement of independent claim 34 calling for at least two “substantially rigid regions,” Sibalís does not teach or suggest modifying the transdermal drug applicator thereof to provide such a construction. It follows that the standing § 103 rejection of these claims based on Sibalís cannot be sustained.

Claims 22, 24 and 26 depend from claim 21. Claim 22 calls for “regions of planar rigidity” having flexural rigidity “greater than about $1.5 \times 10^{-3} \text{ kg-m}^2/\text{rad}$,” claim 24 calls for “rigid regions” having flexural rigidity “greater than about $5.0 \times 10^{-3} \text{ kg-m}^2/\text{rad}$,” and claim 26 calls for a “rigid region” having a flexural rigidity and flexible means having a flexural rigidity, wherein the difference between the two flexural rigidities is “greater than $0.3 \times 10^{-3} \text{ kg-m}^2/\text{rad}$.” Sibalís does not teach or suggest the “rigid region” limitations seemingly called for in claims 22, 24 and 26.² In addition, Sibalís does not teach or suggest the

²We note that the term “the regions of planar rigidity” in claim 22 and the term “the rigid region” in claims 24 and 26 lack a proper antecedent basis. This matter should be corrected upon return of this case to the Technology Center, such as by amending base claim 21 to provide the clear antecedent for the terms in question.

specific difference in flexural rigidity called for in claim 26. Hence, the standing § 103 rejection of these claims based on Sibalis cannot be sustained.

Claims 23 and 25 depend from claim 21 and add that the flexible means has a flexural rigidity of less than about $0.75 \times 10^{-3} \text{ kg-m}^2/\text{rad}$, and of less than about $0.45 \times 10^{-3} \text{ kg-m}^2/\text{rad}$, respectively. On page 10 of the main brief (Paper No. 17), appellants observe that (1) claims 2-6, 22-26, 35-39 and 51-56 require a flexural rigidity defined by the formula $EI = (WL^2)/(2\theta)$, (2) no mention of flexural rigidity is found in Sibalis, and (3) the claim terminology removes the presently claimed invention from the relative term contention of the examiner. Merely pointing out a claim limitation without specifically explaining why that claim language would not have been obvious at the time of the invention to one of ordinary skill in the art in light of the teachings of the applied reference does not constitute a separate argument in favor of patentability. Accordingly, we consider that claims 23 and 25 have not been separately argued apart from claim 21, and on that basis we will sustain the standing § 103 rejection thereof.³

³In any event, the rejection is sound. In this regard, it is clear that Sibalis recognizes the flexibility of the applicator to be a result effective variable for preventing loosening of the applicator from a user's skin (see, for example, column 3, lines 1-39). The determination of an optimum or workable value of an art recognized result effective variable is ordinarily considered to be within the ambit of ordinary skill in the art in the absence of a showing of criticality of the parameter in question. See *In re Woodruff*, 919 F.2d 1575, 1578, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990); *In re Boesch*, 617 F.2d 272, 276, 205 USPQ 215, 219 (CCPA 1980); and *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). In that no evidence of criticality is of record, the teachings of Sibalis would have suggested to those of ordinary skill in the art the

(continued...)

The § 103 rejection of independent claim 51, as well as claims 52-56 that depend therefrom, as being unpatentable over Sibalis will not be sustained. Claim 51 is directed to a body surface mountable electrotransport device comprising, among other things, “a substantially rigid” component having a flexural rigidity greater than $1.5 \times 10^{-3} \text{ kg-m}^2/\text{rad}$. For the reasons discussed above, Sibalis does not teach or suggest a body surface mountable electrotransport device including “a substantially rigid” component within the meaning of that term as used in appellants’ invention.

REMAND

This case is remanded to the examiner for consideration of following matter.

Claims 51, 53 and 56 are directed to a body surface mountable electrotransport device comprising “a substantially rigid” component.⁴ As such, claims 51, 53 and 56 encompass a body surface mounted electrotransport device comprises *a single* substantially rigid component. In the background section of the specification, appellants discussion of the state of the prior art indicates that a body surface mounted electrotransport device comprises a single substantially rigid component was known in the art. In particular, attention is directed to the paragraph spanning pages 4 and 5 of the

³(...continued)
delivery device set forth in claims 23 and 25.

⁴Claim 52 depends from claim 51 and adds that the device of claim 51 has “a plurality of said substantially rigid components” which are coupled together. Claims 54 and 55 depend from claim 52.

specification, wherein appellants state that in order to protect the electronic circuitry in such skin-mounted devices and for a variety of other reasons “these devices have generally utilized *a substantially rigid* container or assembly” (specification, page 5; emphasis added).

The examiner should reevaluate the patentability of claims 51, 53 and 56 in view of above noted prior art, and take whatever action is deemed appropriate in the event it is determined that any of claims 51, 53 and 56 is unpatentable over such the prior art.

SUMMARY

The rejection of claims 1, 7-13, 17-21, 27-30, 34 and 40-47 as being anticipated by Sibalis is reversed as to claims 1, 7-13, 17-20, 30, 34 and 40-47, but is affirmed as to claims 21 and 27-29.

The rejection of claims 2-6, 14-16, 22-26, 31-33, 35-39 and 51-56 as being unpatentable over Sibalis is reversed as to claims 2-6, 14-16, 22, 24, 26, 31-33, 35-39, and 51-56, but is affirmed with respect to claims 23 and 25.

In addition, this case is remanded to the examiner for consideration of the matter noted above.

The decision of the examiner is affirmed-in-part.

In addition to affirming the examiner’s rejection of one or more claims, this decision contains a remand. 37 CFR § 1.196(e) provides that

whenever a decision of the Board of Patent Appeals and Interferences includes or allows a remand, that decision shall not be

considered a final decision. When appropriate, upon conclusion of proceedings on remand before the examiner, the Board of Patent Appeals and Interferences may enter an order otherwise making its decision final.

Regarding any affirmed rejection, 37 CFR § 1.196(b) provides:

Appellant may file a single request for rehearing within two months from the date of the original decision. . . .

The effective date of the affirmance in this case is deferred until conclusion of the proceedings before the examiner unless, as a mere incident to the limited proceedings, the affirmed rejection is overcome. If the proceedings before the examiner does not result in allowance of the application, abandonment or a second appeal, this case should be returned to the Board of Patent Appeals and Interferences for final action on the affirmed rejection, including any timely request for rehearing thereof.

This application, by virtue of its "special" status, requires immediate action, see MPEP § 708.01.

AFFIRMED-IN-PART AND REMANDED

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

CHARLES E. FRANKFORT)	
Administrative Patent Judge)	
)	
)	
)	
)	BOARD OF PATENT
LAWRENCE J. STAAB)	APPEALS
Administrative Patent Judge)	AND
)	INTERFERENCES
)	
)	
)	
JEFFREY V. NASE)	
Administrative Patent Judge)	

LJS/dal

Appeal No. 2001-0661
Application No. 08/480,232

14

Michael, Best & Friedrich, LLP
One South Pinckney Street
P.O. Box 1806
Madison, WI 53701